

Brian Doyle
217 Acacia
El Segundo CA 90245

May 25, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ROCKVILLE MD 20852
Docket No. 98N1265

Dear Elizabeth Hiner:

I object to specific provisions of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999. They effectively jeopardize the opportunity of many consumers to use these valuable products, and to buy the products they choose from the pharmacists their doctors trust most.

Please amend all of section MOU II-C and all of III-C: Distribution of inordinate Amounts of Compounded Drugs. These sections can, by placing restrictions on the amounts that can be sold out of state, discriminate against consumers who do not live in the state where the products preferred by their physicians are compounded. By threatening the economic survival of pharmacies who physicians and customers from out of state by filling prescriptions promptly at affordable prices, the MOU threatens to make the superior products unavailable to consumers who need them and raise their medical costs. Doing so would unfairly restrict consumer choice.

Federal restrictions now in place effectively deny these products to the vast majority of consumers. Section II-B of the MOU refers to restrictions on a compounding pharmacy's right to promote its products and services. The result is that most consumers don't know they exist, and the only physicians who know about them are the enlightened physicians who take the initiative to seek them out.

Please amend the memorandum of understanding as noted above. I want no restrictions on delivery of a compounded medication prescribed for me, regardless of where I live or travel.

Sincerely,


Jacqueline Doyle

98N-1265

cc Senators Boxer and Feinstein, Congressman Kuykendall

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